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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/186,342	11/04/98	CONKLIN	D 97-64

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EXAMINER	
LAZAR WESLEY,E	
ART UNIT	**PAPER NUMBER**
1646	10

DATE MAILED: 01/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/186,342	Applicant(s) Conklin
	Examiner Eliane Lazar-Wesley	Group Art Unit 1646

☒ Responsive to communication(s) filed on *Oct 30, 2000* .

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-14 and 16-25* is/are pending in the application.

Of the above, claim(s) *11-14 and 16-21* is/are withdrawn from consideration.

☒ Claim(s) *10* is/are allowed.

☒ Claim(s) *1-9 and 22-25* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *7*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The amendment filed October 30, 2000, has been entered.

Claims 1-10 and new claims 22-25 are under consideration.

IDS

2. The supplemental IDS filed October 02, 2000, recites "LIFESEQ" references (A35-A129). These references are not publicly available and they will not appear on the face of a patent.

Other references (A6, A8, A10, A11) will not be printed as they don't appear to be complete.

Claim Rejections - 35 USC § 101 and 35 USC § 112, first paragraph

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-9 and 22-25 remain or are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility, for the reasons of record.

The nucleic acid encoding z219c has been obtained by scanning of translated database and confirmation of EST sequence (page 84, example 1).

The specification sets forth various utilities for the claimed nucleic acid and encoded protein; however, none are specific to the nucleic acid claimed. Applicants disclose that, by performing Northern blot analysis, (Example 2, page 85 and page 86), the nucleic acid shows a wide tissue distribution.for z219c (trachea, stomach,colon, pancreas, prostate, small intestine, salivary gland, kidney, fetal kidney, fetal liver, fetal spleen, fetal thymus, and fetal lung). Applicants also show a chromosome localization for z219c (Example 3). While applicants recite that z219c expression has been detected by Northern analysis at various levels in numerous tissues, applicants do not teach where z219c is not expressed. The fact that z219c is expressed in some selected tissues does not exclude *per se* thatz219c is not expressed also in other tissues. One of skill in the art must know where the nucleic acid is not expressed in order for it to be useful , for example in tissue identification.

The assertions of utility are found to be non-specific, as they could apply equally to any nucleic acid or encoded protein obtained from nature, and thus do not fulfill the requirements of 35 U.S.C. 101.

Applicants argue that the polynucleotides of the invention constitute probes that have a diagnostic utility due to their chromosomal localization at 3q21.1-p13.

Applicant's arguments have been considered but have not been found persuasive.for the following reasons: the chromosomal localization claimed for the polynucleotide of the invention spans over a quite large fragment of chromosome 3 (3p21.1-p13 region of chromosome 3), and no specific

localization is provided allowing determination of where the probe actually hybridizes, and if the site of hybridization corresponds to a marker for a specific disease characterized, for example, by a specific deletion or mutation. It is well known in the art that, for chromosomal markers to be specific, they have to map to a specific site, which is supported by the fact that researchers usually need a set of closely spaced markers to assess for example an interstitial break (see for example Shridhar, Oncogene, 14: 1269-77, 1997 at page 1271, col.2). Applicants recite that ARP maps to 3p21.1, and that deletions in ARP are associated with solid tumors of various types, and deletions and mutations at codon 50 are observed in pancreatic tumors. However, there is no evidence that the polynucleotide of the invention maps to the site of ARP, and has any link to ARP. There is no evidence that LOH (loss of heterozygosity) is associated with the polynucleotide of the invention. The argument that a chromosomal deletion of the fragment hybridizing to the probe would provide a specific and well established utility is not persuasive because, although chromosomal deletions or translocations are known to be associated with various tumors (see for example Cigurosa, Genes, chromosomes and cancer 25:123-133, 1999, at page127, col.2), there is no nexus between the claimed nucleic acid and any known deletion, nor sufficient information to allow the use of the claimed nucleic acid for the detection of any deletion or other alteration associated with any known tumor or other condition.

6. Claims 1-9 and 22-25 remain or are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

7. Claims 1, 3, 6-9 remain or are are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record.

Claims 1 and 7 recite a polynucleotide encoding a protein at least 90% identical to amino acid sequence of SEQ ID No:2 from amino acid 23 to 223 (claims 1 and 7). Claim 6 recites a polynucleotide encoding a polypeptide characterized by motifs separated by stretches of undefined amino acids totalling 85-87 amino acids.

(Please note that claim 2 was not meant to be rejected in the former office action (see page 7, paragraph 12, introductory paragraph of the rejection), but that due to a typographical error, claim 2 was incorrectly rejected in the fourth line before the end of page 7).

Applicants arguments have been considered but are not found persuasive, because a nucleotide sequence encoding an amino acid sequence that is 90% identical to the amino acid sequence of SEQ ID No:2, might largely differ in sequence from the nucleotide sequence of SEQ ID No:1. Due to the combination of sequence differences relevant to the percent identity and the codon degeneracy, the nucleic acid encoding a protein that is 90% identical to SEQ ID No:2 might actually differ by 50% from the nucleic acid of SEQ ID No:1.The nucleotide sequence encoding the polypeptide of claim 6 will also differ considerably from the nucleotide sequence of SEQ ID No:1, as the polypeptide of claim 6 might differ by 87 amino acids over the secreted polypeptide of SEQ ID No:2 which is 200 amino acid long, which means a difference of 261 nucleotides over 600. Even

if the nucleotide sequence of SEQ ID No:1 had utility, it is unpredictable which molecule characterized by claims 1, 6 and 7 would have a function, and how to use such a molecule, and if such a molecule could be used for example as a specific hybridization probe. The teachings of the specification are not commensurate in scope with the claims.

8. Claim 10 is allowable.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliane Lazar-Wesley, PhD, whose telephone number is (703) 305 4059. The examiner can normally be reached on Monday-Friday from 9:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308 4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ELW
January 15, 2001

ew

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER